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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,899	02/17/2005	Franz Hammerschmid	PD/4-32578A	8422

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
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EXAMINER

MARTIN, PAUL C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/524,899	HAMMERSCHMID, FRANZ	
	<b>Examiner</b>	<b>Art Unit</b>	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/16/05 and 2/17/</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

Claims 1-9 are pending in this application.

### ***Specification***

The use of the trademarks Bodipy™, Vydac™, and Costar™ has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which may adversely affect their validity as trademarks.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Semicolons should follow the words "...comprising" in line 2 and "...that" in line 16 of the claim. Appropriate correction is required.

Claim 1 is objected to because of the following informalities: The words "to bind" in line 11 should be replaced with the words "of binding". Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross *et al.* (2002).

Ross *et al.* teaches a method for assaying the activity of an enzyme comprising;

Providing a phosphate catalyzing enzyme (Pg.978, Column 1, Lines 19-55 and Column 2, Lines 1-4), providing a peptide (Pg.977, Column 1, Lines 27-29 and Pg.978, Column 1, Lines 1-18), providing a phosphate donor (Pg. 978, Column 2, Line 33), providing candidate compounds (Pg.977, Column 1, Lines 27-29 and Pg.978, Column 1, Lines 1-2), contacting the enzyme with a peptide and phosphate containing donor in the presence or absence of the candidate compounds for a predetermined period of time so that an enzymatic product is formed (Pg.978, Column 2, Lines 27-40 and Pg.980, Fig.2), transferring the enzymatic product formed to a solid phase capable of binding the peptide in the enzymatic product (Pg.978, Column 2, Lines 41-43), determining the presence and amount of the phosphoserine in the bound peptide (Pg. 978, Column 2, Lines 44-55 and Pg. 980, Fig.2).

Ross *et al.* teaches a method wherein the amount of phosphoserine is determined with a phosphoserine recognizing antibody (Pg. 978, Column 2, Lines 11-26).

Ross *et al.* does not teach the use of PAK kinase as the phosphate catalyzing enzyme.

Ross *et al.* does not teach the use of peptides having the amino acid sequences S-S-L-R-A-S-T or A-K-R-R-R-L-S-S-L-R-A-S-T-S-K-S.

Ross *et al.* does not teach a method for differentiating whether an agent modulates the serine, threonine, or both specific activity of a PAK kinase comprising a peptide having the amino acid sequence S-S-L-R-A-S-T and the use of two separate antibodies from a group consisting of a phosphoserine recognizing antibody, a phosphothreonine recognizing antibody, and a phosphoserine and phosphothreonine recognizing antibody.

Ross *et al.* does not teach a method wherein the antibodies bear different labels and the amounts of phosphoserine and phosphothreonine are determined simultaneously.

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize the method taught by Ross *et al.* to any other serine/threonine kinase, including PAK kinase because Ross demonstrates that the method is effective for assaying 15 different phosphate catalyzing enzymes. The ordinary artisan would have been motivated to do so because PAK kinase is thought to be involved with modulating diverse cellular functions the ordinary artisan would have been motivated to detect and explore the modulation of PAK kinase, and would have had a reasonable expectation of success based on the success of the method as practiced by Ross.

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize specific PAK kinase peptides having unique amino acid sequences when applying the method of Ross to examining only PAK kinase rather than the more generic peptide substrates taught by Ross, and would have been motivated to do so because this would serve to increase labeling specificity and ensure more reliable results from the assay. The ordinary artisan would have had a reasonable expectation of success based on the success of Ross in the development and use of more generic peptide tags.

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It would have been obvious to one of ordinary skill in the art to modify the teachings of Ross *et al.* to detect the amount of bound serine and threonine on the bound peptide by using two separate antibodies with separate labels to enable simultaneous determination, and the ordinary artisan would have been motivated to do so because the method of Ross only determines the amount of bound phosphoserine and assaying both residues gives a clearer indication of what types of modifications and role in cell signaling the PAK kinase is involved in. The use of separate labels would have been obvious to the ordinary artisan as a way to differentiate the signals two labeled peptides while simultaneously examination is more efficient than analyzing each separately. The ordinary artisan would have had a reasonable expectation of success based on the success of Ross in creating and using one specific antibody and the fact that both types of antibodies were known in the art at the time of invention (Ross *et al.* Pg.977, Column 2, Lines 9-13).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu *et al.* (2001).

Yu *et al.* teaches the use of PAK kinase as a phosphate catalyzing enzyme (Pg. 244, Column 1, Lines 22-28) in a method comprising a PAK kinase, a peptide (Pg. 244, Column 1, Lines 56-60 and Column 2, Lines 1-13), a phosphate containing donor (Pg.244, Column 2, Line 25), means for detecting phosphothreonine and a solid phase (Pg.244, Column 2, Lines 51-63 and Pg. 245, Column 1, Lines 1-11).

Yu *et al.* does not teach the use of a peptide comprising the amino acid sequence S-S-L-R-A-S-T.

It would have been obvious to one of ordinary skill in the art to modify the teachings of Yu *et al.* to use different amino acid sequences and one would have been motivated to do so because this would serve to make sure that the most specific sequence was used so as to be assured of the highest accuracy in doing the assay, and the ordinary artisan would have had a reasonable expectation of success based on the success of Yu using other amino acid sequences. Further, it is deemed that the compiling of all the components in the method as taught by Yu constitutes, in its broadest reasonable interpretation, a kit.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ng *et al.* (1994).

Ng *et al.* teaches the use of CD45 tyrosine phosphatase as a phosphate catalyzing enzyme (Pg. 178, Column 2, Lines 23-28) in a method comprising a CD45 tyrosine phosphatase, a peptide (Pg. 179, Column 1, Lines 8-28), a phosphate containing donor (Pg. 180, Column 1, Lines 10-11), means for detecting phosphotyrosine and a solid phase (Pg.179, Column 2, Lines 32-41 and Pg.180, Column 1, Lines 1-11).



Ng *et al.* does not teach the use a peptide comprising the amino acid sequences R-N-Q-E-T-Y-E-T-L-K-H or A-E-N-T-I-T-Y-S-L-L-M-H-P. wherein Y is phosphorylated tyrosine.

It would have been obvious to one of ordinary skill in the art to modify the teachings of Ng *et al.* to use different amino acid sequences and one would have been motivated to do so because this would serve to make sure that the most specific sequence was used so as to be assured of the highest accuracy in doing the assay, and the ordinary artisan would have had a reasonable expectation of success based on the success of Ng using other amino acid sequences. Further, it is deemed that the compiling of all the components in the method as taught by Ng constitutes, in its broadest reasonable interpretation, a kit.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**No Claims are allowed.**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin  
Examiner  
Art Unit 1655

02/02/06

PATRICIA LEITH  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Patricia Leith', written over the printed name and title.